10-27-05

Patent / Docket No. 23100 40
Customer No. 27683

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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In re application of:

McANALLEY, B.

Serial No.: 10/001,439

Filed: October 25, 2001

For: DIETARY SUPPLEMENT

COMPOSITIONS

Mail Stop Appeal Brief - Patents Commissioner For Patents P.O. Box 1450 Alexandria, VA 22313-1450 Group Art Unit: 1654

Examiner: Coe, Susan D.

EXPRESS MAIL NO.: EV369 675 495

DATE OF DEPOSIT: 10/26/200

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Sir:

Enclosed are the following regarding the above-identified patent application:

- 1. Appeal Brief;
- 2. filing fee in the amount of \$500.00; and
- 3. return postcard.

The Commissioner is hereby authorized to charge payment of any further fees associated with any of the papers submitted herewith or to credit any overpayment to Deposit Account No. 08-1394.

Respectfully submitted,

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Confirmation No. 2421

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MAIL STOP APPEAL BRIEF - PATENTS

Board of Patent Appeals and Interferences United States Patent and Trademark Office P.O. Box 1450

Alexandria, VA 22313-1450

APPEAL BRIEF

This Brief is submitted in connection with an appeal from the final rejection of the Examiner dated May 27, 2005, finally rejecting claims 1, 8-17 and 19, which constitute all of the pending claims in this application.

REAL PARTY IN INTEREST

The real party in interest is Mannatech, Inc., a Texas corporation, with its principal office at 600 South Royal Lane, Suite 200, Coppell, Texas 75019.

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RELATED APPEALS AND INTERFERENCES

There are no prior or pending related appeals, interferences or judicial proceedings known to appellant, the appellant's legal representative, or assignee which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

The status of all of the claims in the proceeding is as follows:

Claims 1, 8-17 and 19 are rejected.

Claims 2-7, 18 and 20-27 have been cancelled.

Claims 1, 8-17 and 19 are on appeal here.

The text of claims 1, 8-17 and 19 is set forth in the Claims Appendix attached hereto.

STATUS OF AMENDMENTS

No amendments were filed in response to the final rejection dated May 27, 2005.

SUMMARY OF CLAIMED SUBJECT MATTER

The claimed subject matter, as set forth in the only independent claim in this appeal, claim 1, is a dietary supplement composition (U.S. Patent Publication No. 2002/0119928, Page 6, paragraph [0051], lines 1-3 and Page 6, paragraph [0052], lines 1-3). The claimed dietary supplement composition includes a nutritionally effective amount of β-glucan (*Id.*, Page 7, paragraph [0066], lines 1-9), colostrum (*Id.*, Page 7, paragraph [0062], lines 1-35), lactoferrin

(*Id.*, Page 7, paragraph [0063], lines 1-19), citrus pectin (*Id.*, Page 7, paragraph [0064], lines 1-6) and a complex of essential saccharides (*Id.*, Page 6, paragraph [0058], lines 5-9).

When absorbed in combination, the effects of β-glucan, colostrum and lactoferrin on the health and well-being of the recipient are surprisingly beneficial, including: promotion of immune system health, promotion of body health and athletic performance, promotion of gastrointestinal (GI) tract health, promotion of blood vessel health, promotion of glucose utilization and blood sugar balance, improved pathogen resistance, improved cancer inhibition and improved mental function and toxin-related activities (*Id.*, Page 6, paragraph [0051], lines 5-14). The combination of such compositions with citrus pectin and a complex of essential saccharides provides additional benefits (*Id.*, Page 7, paragraph [0064] and Pages 6-7, paragraph [0058]).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1, 8-17 and 19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,576,015 to Donzis (hereafter referred to as "Donzis '015"), U.S. Patent No. 5,531,989 to Paul (hereafter referred to as "Paul '989") and International Publication No. WO 97/05884 to Plaut (hereafter referred to as "Plaut '884").

ARGUMENT

Test for Obviousness Under 35 U.S.C. § 103(a)

To sustain the rejection of claims 1, 8-17 and 19 under 35 U.S.C. § 103(a), a *prima facie* case of obviousness must be established. According to Section 2142 of the Manual of Patent

Examining Procedure ("MPEP § 2142"), to establish a prima facie case of obviousness, the following three basic criteria must be met:

- (1) There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings;
 - (2) There must be a reasonable expectation of success; and
 - (3) The prior art references must teach or suggest all the claim limitations.

Also according to MPEP § 2142:

To reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art. (emphasis added).

The Rejection

Donzis '015 was cited as allegedly teaching that beta-glucan from yeast cell walls enhances host immune resistance to diseases caused by bacterial and viral infection. In this regard, the Examiner cited column 1, lines 20-38 of Donzis '015.

Paul '989 was cited as allegedly teaching a composition containing lactoferrin, pectin and saccharides that enhances the immune system and treats diseases caused by bacteria, viruses, fungi, and parasites. In this regard, the Examiner cited column 3, lines 32-50 of Paul '989.

Plaut '884 was cited as allegedly teaching that lactoferrin and colostrum strengthen the immune system and treat diseases caused by bacterial and viral infections. In this regard, the Examiner cited page 3, second paragraph of Plaut '884.

In the Office Action mailed May 27, 2005 (there was no Paper Number associated with the Office Action), the Examiner alleged that Donzis '015, Paul '989 and Plaut '884:

[S]how that it was well known in the art at the time of the invention that all of the claimed ingredients, essential saccharides, lactoferrin, colostrum and citrus pectin, were known to enhance a patient's immune response and to treat bacterial and viral infections. (Office Action mailed May 27, 2005, page 3).

The Examiner cited MPEP § 2144.06 for the proposition that:

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. ... [T]he idea of combining them flows logically from their having been individually taught in the prior art. (MPEP § 2144.06.) (Id., at 2).

Based upon MPEP § 2144.06, the Examiner contended that:

Since it has been well established that it is obvious to combine two or more ingredients that are known to be used for the same purpose, it is obvious to combine the compositions taught by the prior art into one composition. (*Id.*, at 3).

The Examiner further argued that:

Motivation for such a combination stems from the teaching of equivalence of the ingredients in the art for the dual purposes of enhancing the immune system and treating bacterial and viral diseases. (*Id.*).

Finally, in response to the Applicant's consistent arguments throughout the prosecution of this application that the Examiner's conclusion of obviousness of the claimed subject matter over the combination of Donzis '015, Paul '989 and Plaut '884 was based upon a hindsight reconstruction of the claimed subject matter, the Examiner stated that:

[I]t must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. (*Id.*).

Applicant's Traversal of the Rejection

For the following reasons, it is clear that the Examiner did not support factually a *prima* facie case of obviousness of claims 1, 8-17 and 19 based on Donzis '015, Paul '989 and Plaut '884.

The Art Cited Fails to Teach or Suggest All the Claim Limitations.

Applying the criteria set forth in MPEP § 2142, none of Donzis '015, Paul '989 and Plaut '884 disclose or suggest all of the limitations of claims 1, 8-17 and 19.

Donzis '015 merely discloses the use of beta (1,3) yeast extract glucan particles as nutritional supplements. Contrary to the claimed subject matter, however, Donzis '015 does not disclose or suggest a composition that includes a nutritionally effective amount of beta glucan, colostrum, citrus pectin and a complex of essential saccharides.

Paul '989 merely discloses an immunoglobulin and fiber-containing composition for use as a dietary supplement for restoring and maintaining gastrointestinal health. Paul '989 discloses that the fiber portion of the dietary supplement may include inulin, fructo-oligosaccharides, pectin, guar gum and mixtures thereof and that the dietary supplement may include lactoferrin as an inhibitor of detrimental iron-catalyzed processes, however, Paul '989 fails to disclose or suggest a composition that includes a nutritionally effective amount of beta glucan, colostrum, citrus pectin and a complex of essential saccharides.

Plaut '884 merely discloses an infant formula that includes pasteurized milk, active lactoferrin, and an antibody which specifically binds at least one of an IgA protease and an IgA protease precursor. Contrary to the claimed subject matter, however, Plaut '884 does not disclose or suggest a composition that includes a nutritionally effective amount of beta glucan, colostrum, citrus pectin and a complex of essential saccharides.

Donzis '015, Paul '989 and Plaut '884 fail to teach, motivate or suggest all of the limitations of independent claim 1 or the claims dependent thereon, namely, claims 8-17 and 19. Therefore, the third criterion of a *prima facie* case of obviousness set forth in MPEP § 2142 is not met because none of the references, alone or in combination teach each and every element of the claimed invention.

Improper Combination or Modification of Donzis '015, Paul '989 and Plaut '884.

Applying the criteria set forth in MPEP § 2142, it is improper to combine or modify Donzis '015, Paul '989 and Plaut '884 to support a rejection of claims 1, 8-17 and 19 under 35 U.S.C. § 103(a) because the references fail the current test for obviousness. Specifically, MPEP § 2143.01, provides that:

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. ... The mere fact that references <u>can</u> be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.

Since the Federal Circuit first addressed this issue in ACS Hosp. Systems, Inc. v. Montefiore Hosp., 221 USPQ 929 (Fed. Cir. 1984), the Court has consistently held that:

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined only if there is some suggestion or incentive to do so.

Id. at 933 (emphasis added).

The case law is clear that the record must include direct evidence that a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed. A rejection cannot be predicated on the mere identification of individual

components of claimed limitations absent some teaching or suggestion supporting the combination. Rather, particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed. Ecolochem Inc. v. Southern California Edison, 56 USPQ2d 1065, 1076 (Fed. Cir. 2000). Here, no such evidence was presented and made of record. There is nothing in the text of Donzis '015, Paul '989 and Plaut '884 that would lead the skilled artisan to select the elements of the invention, without using the present specification as a template. There is simply no evidence anywhere in the record to support the combination of Donzis '015, Paul '989 and Plaut '884.

Current case law makes it clear that the best defense against a hindsight-based obviousness analysis is the rigorous application of the requirement for a showing of a teaching or motivation to combine the prior art references. For example, in *In re Dembiczak*, 50 USPQ2d 1614 (Fed. Cir. 1999), the Federal Circuit noted that:

[c]ombining prior art references without *evidence* of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability – the essence of hindsight.

Id. at 1617.

In addition, the Federal Circuit has recognized that the "standards for the patenting of chemical entities have evolved." In re Mayne, 41 USPQ 2d 1451, 1453-54 (Fed. Cir. 1997) (emphasis added). When relying on numerous references or a modification of prior art, "it is incumbent upon the examiner to identify some suggestion to combine references or make the modification." Id. (emphasis added).

In the present case, it is clear that there are hundreds of ingredients that are alleged to strengthen the immune system. To argue that the claimed combination is obvious in light of the

hundreds of possible ingredients is the epitome of impermissible hindsight. Without the use of such hindsight, which the Examiner <u>admits</u>, the Examiner cannot maintain that the combination as claimed is obvious in light of the prior art. It is respectfully submitted that the only way Donzis '015, Paul '989 or Plaut '884 could be pieced together to defeat patentability is indeed to use Applicant's disclosure as a blueprint.

As noted above, the Examiner cited MPEP § 2144.06 to support the combination of Donzis '015, Paul '989 and Plaut '884. However, MPEP § 2144.06 also states:

But see In re Geiger, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987) (Based upon the prior art and the fact that each of the three components of the composition used in the claimed method is conventionally employed in the art for treating cooling water systems, the board held that it would have been prima facie obvious, within the meaning of 35 U.S.C. 103, to employ these components in combination for their known functions and to optimize the amount of each additive.... Appellant argues ... hindsight reconstruction or at best,... "obvious to try".... We agree with appellant.) (Emphasis added).

The actual quotation from the Federal Circuit's decision in *In re Geiger* which involved facts very similar to the present case, reads as follows:

Appellant contends that the PTO failed to establish a prima facie case of obviousness and, consequently, that the board's affirmance of the examiner's rejections was erroneous. Appellant argues that the PTO's position represented hindsight reconstruction or, at best, established that it would have been 'obvious to try' various combinations of known scale and corrosion prevention agents, including the combination recited in the appealed claims.

We agree with the appellant that the PTO has failed to establish a prima facie case of obviousness. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination.

In re Geiger, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987).

Accordingly, rather than support the Examiner's proposition, MPEP § 2144.06 acknowledges that the Federal Circuit has rejected the Examiner's proposition and instead requires application of the ACS Hospital Systems test for the combination of references, viz., that

references can be combined only if there is some suggestion, motivation or incentive for the combination. This test must be followed in all cases.

At best, the Examiner's reasoning for the combination of Donzis '015, Paul '989 and Plaut '884 in this case, is based upon the outdated "obvious to try" test referred to in the *Geiger* decision. According to this outdated test, if two ingredients are useful for the same purpose, then it is obvious to try to combine the ingredients. However, the "obvious to try" test is <u>not</u> the current standard for obviousness. Indeed, in *In re Geiger*, the Federal Circuit stated:

At best, in view of these disclosures, one skilled in the art might find it obvious to try various combinations of these known scale and corrosion prevention agents. However, this is not the standard of 35 U.S.C. §103.

In re Geiger, 2 USPQ 2d 1276, 1278 (Fed. Cir. 1987) (emphasis added).

Instead, the current test for establishing the obviousness of a claimed invention is described in *In re Dembiczak* as follows:

Our analysis begins in the text of section 103 ..., with the phrase "at the time the invention was made." For it is this phrase that guards against entry into the tempting but forbidden zone of hindsight, ... when analyzing the patentability of claims pursuant to that section. Measuring a claimed invention against the standard established by section 103 requires the oft difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then accepted wisdom in the field. ... Close adherence to this methodology is especially important in the case of less technologically complex inventions, where the very ease with which the invention can be understood may prompt one to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher. ... In this case, the Board fell into the hindsight trap. ... The range of sources available, however, does not diminish the requirement for actual evidence. That is, the showing must be clear and particular.

In re Dembiczak, 50 USPQ 2d 1614, 1616-17 (Fed. Cir. 1999) (emphasis added).

The Examiner has not presented any evidence on the record to support that the skilled artisan, reading Donzis '015, Paul '989 and Plaut '884, would be motivated to combine the

references. The Examiner's bare assertion for the motivation to combine the references "stems from the teaching of equivalence of the ingredients in the art for the dual purposes of enhancing the immune system and treating bacterial and viral diseases" (Office action mailed May 27, 2005, page 3). However, bare assertions are not the clear and particular "evidence" required by the Federal Circuit under current law. Since no such evidence has been supplied, it is apparent that the combination of Donzis '015, Paul '989 and Plaut '884 is based solely upon an impermissible hindsight reconstruction of the subject matter of claims 1, 8-17 and 19.

Indeed, the only evidence of record concerning the combination of Donzis '015, Paul '989 and Plaut '884 is the Examiner's admission of the impermissible use of hindsight in fashioning the combination. Specifically, the Examiner <u>admits</u> the use of hindsight, but attempts to justify the use of such impermissible hindsight by arguing <u>on the record</u> that "any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning." (Office Action mailed May 27, 2005, page 3). Cleary, the Examiner used the present specification and claims as a blueprint so as to combine Donzis '015, Paul '989 and Plaut '884 in the right way to achieve the subject matter of claims 1, 8-17 and 19. None of the three references mentions, suggests, teaches, motivates or points the skilled artisan to one or the other reference.

In support of the Examiner's assertion that it is permissible to use hindsight, the Examiner cited *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971) — a thirty four year old case that does not reflect the current state of the law. Instead, the current state of the law forbids <u>any</u> use of hindsight, as stated below:

This court forbids the use of hindsight in the selection of references that comprise the case of obviousness.

In re Rouffet, 47 USPQ 2d 1453, 1458 (Fed. Cir. 1998) (emphasis added).

Thus, it is respectfully submitted that the Examiner has used an outdated and impermissible standard to justify the use of hindsight in connection with the combination of Donzis '015, Paul '989 and Plaut '884.

Moreover, there is no suggestion or motivation to modify any of Donzis '015, Paul '989 or Plaut '884 to include all of the limitations of any of claims 1, 8-17 and 19. Specifically, as noted above, none of Donzis '015, Paul '989 or Plaut '884 disclose or suggest a composition that includes each of β -glucan, colostrum, lactoferrin, citrus pectin and a complex of essential saccharides. Also, none of Donzis '015, Paul '989 or Plaut '884 recognize the myriad of beneficial effects on the health and well-being of a recipient that are realized upon the absorption in combination of β -glucan, colostrum, lactoferrin, citrus pectin and a complex of essential saccharides.

Therefore, it would be improper to modify any of Donzis '015, Paul '989 or Plaut '884 in an attempt to achieve all of the limitations of claims 1, 8-17 and 19 because there is no motivation or suggestion, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the teachings of such references.

For the foregoing reasons, the first criterion of a *prima facie* case of obviousness set forth in MPEP § 2142 has not been met because there is no motivation or suggestion, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the teachings of such references to achieve all of the limitations of claims 1, 8-17 and 19.

There Is No Reasonable Expectation of Success.

Applying the criteria set forth in MPEP § 2142, there is no reasonable expectation that the modification or combination of Donzis '015, Paul '989 and Plaut '884 would successfully achieve the subject matter of claims 1, 8-17 and 19.

As noted above, there is no motivation or suggestion, either in Donzis '015, Paul '989 and Plaut '884 or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the teachings of such references to achieve all of the limitations of claims 1, 8-17 and 19. Without such a suggestion or motivation for modification or combination of Donzis '015, Paul '989 or Plaut '884, the second criterion of a *prima facie* case of obviousness set forth in MPEP § 2142 is not been met because there could be no reasonable expectation of success.

Conclusion.

In view of the above, Applicant submits that none of the three criteria of a *prima facie* case of obviousness is satisfied with respect to claims 1, 8-17 and 19 in view of Donzis '015, Paul '989 and Plaut '884. Accordingly, it is clear that the rejection of claims 1, 8-17 and 19 under 35 U.S.C. §103(a) over the combination of Donzis '015, Paul '989 and Plaut '884 is improper and should be withdrawn.

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For all of the foregoing reasons, claims 1, 8-17 and 19 are in condition for allowance. Favorable reconsideration of claims 1, 8-17 and 19 is respectfully requested.

Respectfully submitted,

Date: 10/26/05

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CLAIMS APPENDIX

- 1. (Previously Presented) A dietary supplement composition for a mammal, comprising a nutritionally effective amount of β -glucan, colostrum, lactoferrin, citrus pectin and a complex of essential saccharides.
- 8. (Previously Presented) The dietary supplement composition of claim 1 wherein said mammal is a human.
- 9. (Previously Presented) The dietary supplement composition of claim 1 wherein said composition comprises from about 5 to about 83.3 weight percent of said colostrum, from about 0.909 to about 6.67 weight percent of said lactoferrin, from about 0.1 to about 1.25 weight percent of said citrus pectin, and from about 0.001 to about 10 weight percent of said β-glucan.
- 10. (Previously Presented) The dietary supplement composition of claim 1 further comprising a nutritionally effective amount of citric acid.
- 11. (Previously Presented) The dietary supplement composition of claim 10, wherein said composition comprises from about 0.25 to about 2.4 weight percent of said citric acid.
- 12. (Previously Presented) The dietary supplement composition of claim 1 further comprising a nutritionally effective amount of citric acid, dextrose, magnesium stearate, silicon dioxide and stearic acid.
- 13. (Previously Presented) The dietary supplement composition of claim 12, wherein said composition comprises from about 0.25 to about 2.4 weight percent of said citric acid, from about 35.8 to about 88.3 weight percent of said dextrose, from about 0.25 to about 1.5 weight percent of said magnesium stearate, from about 0.25 to about 1.5 weight percent of said silicon dioxide, and about 1.67 to about 2.5 weight percent of said stearic acid.
- 14. (Previously Presented) The dietary supplement composition of claim 12, further comprising one or more of a nutritionally acceptable carrier, diluent or flavoring.

- 15. (Previously Presented) The dietary supplement composition of claim 13, further comprising a flavoring in an amount of about 0.15 to about 1.31 weight percent.
- 16. (Previously Presented) The dietary supplement composition of claim 1 wherein said composition is prepared in a chewable delivery system.
- 17. (Previously Presented) The dietary supplement composition of claim 14 wherein said composition comprises about 9.63 weight percent of said colostrum, about 0.642 weight percent of said lactoferrin, about 0.321 weight percent of said citrus pectin, about 1.28 weight percent of said β-glucan, about 0.626 weight percent of said citric acid, about 83.3 weight percent of said dextrose, about 0.482 weight percent of said magnesium stearate, about 0.482 weight percent of said silicon dioxide, about 1.93 weight percent of said stearic acid, and about 1.31 weight percent of said nutritionally acceptable carrier, diluent, or flavoring.
- 19. (Previously Presented) The dietary supplement composition of claim 1, wherein the complex of essential saccharides comprises saccharides provided in oligomeric or polymeric forms as found in: gum tragacanth, guar gum, grain flour, rice flour, sugar cane, beet sugar, potato, milk, agar, algin, locust bean gum, psyllium, karaya gum, seed gums, Larch tree extract, aloe vera extract, gum ghatti, starch, cellulose, degraded cellulose, fructose, high fructose corn syrup, pectin, chitin, acacia, gum arabic, alginic acid, carrageenan, dextran, xanthan gum, chondroitin sulfate, sucrose, acetylated polymannose, maltose, glucan, lentinan, mannan, levan, hemi-cellulose, inulin, fructan, and lactose.

EVIDENCE APPENDIX

NONE.

RELATED PROCEEDINGS APPENDIX

NONE.